

Attorney Docket No. 60020830-0004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:) Group Art Unit:
)
 Tze Chein Wuñ) Examiner:
)
 Application No. 10/516,908)
)
 Filed: December 3, 2004)
)
 For: Novel Recombinant Anticoagulant)
 Proteins)
)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

Transmittal of Information Disclosure Statement
Application No. 10/516,908
Page 2

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Respectfully submitted,

Dated: 1/28/2005

By: Tara A. Nealey, Ph.D.
Tara A. Nealey, Ph.D.
Registration No. 42,927
SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. Box 061080
Wacker Drive Station, Sears Tower
Chicago, Illinois 60606-1080
(312) 876-8000

Substitute for form 1449B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	10/516,908
			Filing Date	December 3, 2004
			First Named Inventor	Tze Chien Wun
			Art Unit	
			Examiner Name	
Sheet	1	of 4	Attorney Docket Number	60020830-0004
OTHER ITEMS – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	1	BACH et al., Expression of tissue factor procoagulant activity: Regulation by cytosolic calcium. Proc Natl Acad Sci USA 1990; 87: 6995-9.		
	2	BEVERS et al., Generation of prothrombin-converting activity and the exposure of phosphotidylserine at the outer surface of platelets. Eur J Biochem 1982; 122: 429-36.		
	3	BOMBELI et al., Apoptotic vascular endothelial cells become procoagulant. Blood 1997; 89: 2429-42.		
	4	BROZE, Tissue factor pathway inhibitor and the current concept of blood coagulation. Blood Coagul Fibrinol 1995; 6: 7-13.		
	5	CHASE et al., Titration of trypsin, plasmin, and thrombin with <i>p</i> -nitrophenyl <i>p</i> '-guanidinobenzoate HCl. Methods Enzymol 1970; 19: 20-7.		
	6	DACHARY-PRIGENT et al., Physiopathological significance of catalytic phospholipids in the generation of thrombin. Sem Thromb Hemost 1996; 22: 157-64.		
	7	DENNIS et al., Kunitz domain inhibitors of tissue factor-factor VIIa. I. Potent inhibitors selected from libraries by phage display. J Biol Chem 1994; 269: 22129-36.		
	8	DENNIS et al. Kunitz domain inhibitors of tissue factor-factor VIIa. II. Potent and specific inhibitors by competitive phage selection. J Biol Chem 1994; 269: 22137-44.		
	9	DIAZ-COLLIER et al., Refold and characterization of recombinant tissue factor pathway inhibitor expressed in <i>E. coli</i> . Thromb Haemost 1994; 71: 339-46.		
	10	FRANSSEN et al., Prothrombinase is protected from inactivation by tissue factor pathway inhibitor: competition between prothrombin and inhibitor. Biochem J 1997; 323: 33-7.		
	11	GILL et al., Calculation of protein extinction coefficients from amino acid sequence data. Anal Biochem 1989; 182: 319-26.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1540, Alexandria, VA 22113-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449B/PTO			<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	10/516,908
			Filing Date	December 3, 2004
			First Named Inventor	Tze Chien Wun
			Art Unit	
			Examiner Name	
Sheet	2	of 4	Attorney Docket Number	60020830-0004
OTHER ITEMS – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	12	GIRARD et al., Inhibition of factor VIIa-tissue factor coagulation activity by a hybrid protein. <i>Science</i> 1990; 248: 1421-4.		
	13	GIRARD, Tissue factor pathway inhibitor. In Sasahara AA, Loscalzo J (eds): <i>New Therapeutic Agents in Thrombosis and Thrombolysis</i> . New York, Marcel Dekker, 1997: 225-260.		
	14	GREENO et al., Apoptosis is associated with increased cell surface tissue factor procoagulant activity. <i>Lab Invest</i> 1996; 75: 281-9.		
	15	HANSEN et al., Discordant expression of tissue factor and its activity in polarized epithelial cells. Asymmetry in anionic phospholipid availability as a possible explanation. <i>Blood</i> 1999; 94: 1657-64.		
	16	HASKEL et al., Prevention of arterial reocclusion after thrombolysis with recombinant lipoprotein-associated coagulation inhibitor. <i>Circulation</i> 1991; 84: 821-7.		
	17	HOFFMAN et al., Factors IXa and Xa play distinct roles in tissue factor-dependent initiation of coagulation. <i>Blood</i> 1995; 86:1794-801.		
	18	JANG et al., Influence of blockade at specific levels of the coagulation cascade on restenosis in a rabbit atherosclerotic femoral artery injury model. <i>Circulation</i> 1995; 92: 3041-50.		
	19	KINSKY, Preparation of liposomes and a spectrometric assay for release of trapped glucose marker. <i>Methods Enzymol.</i> 1974; 32: 501-514.		
	20	KRISHNASWAMY et al., Role of the membrane surface in the activation of human coagulation factor X. <i>J Biol Chem</i> 1992; 267: 26110-20.		
	21	LE et al., Studies of the mechanism for enhanced cell surface factor VIIa/tissue factor activation of factor X on fibroblast monolayers after their exposure to N-ethylmaleimide. <i>Thromb Haemost</i> 1994; 72: 848-55.		
	22	LEFOVITS et al., Selection inhibition of factor Xa is more efficient than factor VIII tissue factor complex blockade at facilitating coronary thrombolysis in the canine model. <i>J. Am. Coll. Cardiol.</i> 1996; 28: 1858-65.		
	23	MCGRATH et al., Ecotin: lessons on survival in a protease-filled world. <i>Protein Sci</i> 1995; 4:141-8.		
	24	MAHDI et al., Protease nexin-2/amyloid beta-protein precursor inhibits factor Xa in the prothrombinase complex. <i>J Biol Chem</i> 1995; 270: 23468-74.		
	25	MAHDI et al., Protease nexin-2/amyloid \square -protein precursor regulates factor VIIa and the factor VIIa-tissue factor complex. <i>Thromb Res</i> 2000; 99: 267-76.		

Substitute for form 1449B/PTO			<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	10/516,908
			Filing Date	December 3, 2004
			First Named Inventor	Tze Chien Wun
			Art Unit	
			Examiner Name	
Sheet	3	of 4	Attorney Docket Number	60020830-0004
OTHER ITEMS – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	26	MANN, Biochemistry and physiology of blood coagulation. Thromb Haemost 1999; 82: 165-74.		
	27	MAST et al., Physiological concentrations of tissue factor pathway inhibitor do not inhibit prothrombinase. Blood 1996; 87: 1845-50.		
	28	MONROE et al., The factor VII-platelet interplay: effectiveness of recombinant factor VIIa in the treatment of bleeding in severe thrombocytopathia. Sem Thromb Haemost 2000; 26: 373-7		
	29	MORRISEY, Tissue factor: An enzyme cofactor and a true receptor. Thromb Haemost 2001; 86: 66-74.		
	30	NEEPER et al., Characterization of recombinant tick anticoagulant peptide. J. Biol. Chem. 1990; 265: 17446-52.		
	31	OZBECK et al., Topical tissue factor pathway inhibitor improves free flap survival in a model simulating free flap errors. J Reconstr Microsurg 1995; 11: 185-188.		
	32	PETERSEN et al., Inhibitory properties of separate recombinant Kunitz-type-protease-inhibitor domains from tissue factor pathway inhibitor. Eur J Biochem 1996; 235, 310-6.		
	33	RAND et al., Blood clotting in minimally altered whole blood. Blood 1996; 88: 3432-45.		
	34	REUTELINGSPERGER et al., Annexin V, the regulator of phosphatidylserine-catalyzed inflammation and coagulation during apoptosis. Cell Mol Life Sci 1997; 53: 527-32.		
	35	ROMISCH et al., <i>In vivo</i> antithrombotic potency of placenta protein 4 (annexin V). Thromb Res 1991; 61: 93-104.		
	36	SCHMAIER et al., Factor IXa inhibition by protease nexin-2/amyloid beta-protein precursor on phospholipid vesicles and cell membranes. Biochemistry 1995; 34: 1171-8.		
	37	SCHMAIER et al., Protease Nexin-2/Amyloid β protein precursor. A tight-binding inhibitor of coagulation factor IXa. J Clin Invest 1993; 2540-5.		
	38	SCORER et al., Rapid selection using G418 of high copy number transformants of <i>Pichia pastoris</i> for high-level foreign gene expression. Biotechnology 1994; 12: 181-4.		
	39	SHI, Lactadherin inhibits enzyme complexes of blood coagulation by competing for phospholipid-binding sites. Blood 2003; 101:2628-36.		
	40	SIMS et al., Unraveling the mysteries of phospholipid scrambling. Thromb Haemost 2001; 86: 266-75.		

Substitute for form 1449B/PTO			<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	10/516,908
			Filing Date	December 3, 2004
			First Named Inventor	Tze Chien Wun
			Art Unit	
			Examiner Name	
Sheet	4	of 4	Attorney Docket Number	60020830-0004
OTHER ITEMS – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	41	SMITH, Titration of activated bovine factor X. J Biol Chem 1973; 248: 2418-23.		
	42	SMITH et al., Platelet coagulation factor XIa inhibitor, a form of Alzheimer amyloid precursor protein. Science 1990; 248: 1126-8.		
	43	STANSSENS et al., Anticoagulant repertoire of the hookworm <i>Ancylostoma caninum</i> . Proc Natl Acad Sci USA 1996; 93: 2149-54.		
	44	STASSEN et al., Characterization of a novel series of aprotinin-derived anticoagulants. I. <i>In vitro</i> and pharmacological properties. Thromb Haemost 1995; 74: 646-54.		
	45	STASSEN et al., Characterization of a novel series of aprotinin-derived anticoagulants. II. Comparative antithrombotic effects on primary thrombus formation <i>in vivo</i> . Thromb Haemost 1995; 74: 655-59.		
	46	TAIT et al., Evaluation of annexin V as a platelet-directed thrombus targeting agent. Thromb Res 1994; 75: 491-501.		
	47	THIAGARAJAN et al., Inhibition of arterial thrombosis by recombinant annexin V in a rabbit carotid artery injury model. Circulation 1997; 96: 2339-47.		
	48	TUSZYNSKI et al., Isolation and characterization of antistasin. J Biol Chem 1987; 262: 9718-23.		
	49	VAN RYN et al., The effect of heparin and annexin V on fibrin accretion after injury in the jugular vein of rabbit. Thromb Haemost 1993; 69: 227-30.		
	50	WAXMAN et al., Tick anticoagulant peptide is a novel inhibitor of blood coagulation factor Xa. Science 1990; 248: 593-6.		
	51	WUN et al., Comparison of recombinant tissue factor pathway inhibitors expressed in human SK hepatoma, mouse C127, baby hamster kidney, and Chinese hamster ovary cells. Thromb Haemost 1992; 68: 54-9.		
	52	ZWAAL et al., Lipid-protein interactions in blood coagulation. Biochim Biophys Acta 1998; 1376: 433-53		
	53	ZWAAL et al., Pathophysiological implications of membrane phospholipid asymmetry in blood cells. Blood 1997; 89: 1121-32.		

Examiner Signature	Date Considered
--------------------	-----------------